

CLAIMS

1. Use of water to control particle size in a process for the production of particles for use in a pharmaceutical composition, said process comprising:
  - 5 mixing water with a component composition comprising at least a rheology modifying agent to produce a paste;
  - extruding at least a portion of the paste to form extrudate;
  - 10 spheronising at least a portion of the extrudate to form spheronised particles; and
  - drying at least a portion of the spheronised particles.
2. Use as claimed in Claim 1 wherein water is used in an amount of between from about 180 wt % to about 190 wt % of the component composition.
3. Use as claimed in Claim 1 or Claim 2 wherein water is used in an amount of about 185 wt % of the component composition.
4. Use as claimed in any of Claims 1 to 3 wherein between from about 80 % to about 98 % of particles have a diameter between the range of about 800 to about 1500  $\mu\text{m}$ .
5. Use as claimed in any of the preceding claims wherein between from about 95 % to about 98 % of particles have a diameter between the range of about 800 to about 1500  $\mu\text{m}$ .
6. Use as claimed in Claim 3 wherein use of 5 wt % more water increases particle size such that substantially all of the particles have a diameter over 1500  $\mu\text{m}$ .
7. Use as claimed in any of the preceding claims wherein the dry particles are screened to obtain particles having a diameter with the range of about 800 to about 1500  $\mu\text{m}$ .

8. Use as claimed in any of the preceding claims wherein the composition further comprises a therapeutically active compound selected from peptides, polypeptides, proteins, interferons, TNF antagonists, protein and peptide agonists and antagonists of the immune system, hormones, cytokines and cytokine agonists and antagonists, analgesics, antipyretics, antibacterial and antiprotozoal agents, anti-infective agents, antibiotics, antiviral agents, antifungal agents, antimalarial agents, anti-inflammatory agents, steroids, probiotics and prebiotics, opiate agonists and antagonists, bisphosphonates, anticancer and cytotoxic agents, immunomodulators, antiparasitic agents and pharmacologically acceptable salts and derivatives of each of these actives.
9. Use as claimed in any of the preceding claims wherein the composition further comprises a therapeutically active compound selected from erythropoietin, human growth hormone, metronidazole, albenazole, mebendazole, praziquantel, clarithromycin, gentamycin, ciprofloxacin, rifabutin, 5-aminosalicylic acid, 4-aminosalicylic acid, balsalazide, prednisolone metasulphobenzoate,  $\alpha$ -amylase, paracetamol, metformin, cyclophosphamide, cisplatin, vincristine, methotrexate, azathioprine and cyclosporin or pharmacologically acceptable salts or derivatives thereof.
10. Use as claimed in Claim 9 or Claim 10 wherein the therapeutically active compound is prednisolone or a pharmacologically acceptable salt or derivative thereof.
11. Use as claimed in Claim 9 or Claim 10 wherein the therapeutically active compound is metronidazole or a pharmacologically acceptable salt or derivative thereof.
12. Use as claimed in Claim 9 or Claim 10 wherein the therapeutically active compound is erythropoietin or a pharmacologically acceptable salt or derivative thereof.

13. Use as claimed in any of Claims 8 to 12 wherein the therapeutically active compound is present in the composition in a therapeutic amount.

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14. Use as claimed in any of Claim 8 to 13 wherein the therapeutically active compound is present in an amount between from more than 0 wt % to about 90 wt% of the component composition.

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15. Use as claimed in any of Claim 8 to 14 wherein the therapeutically active compound is present in an amount between from more than 0 wt % to about 40 wt% of the component composition.

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16. Use as claimed in any of Claim 8 to 15 wherein the therapeutically active compound is present in an amount between from about 5 wt % to about 20 wt% of the component composition.

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17. Use as claimed in any of Claim 8 to 15 wherein the therapeutically active compound is present in an amount between from more than 0 wt % to about 1 wt % of the component composition.

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18. Use as claimed in any of the preceding claims wherein the rheology modifying agent comprises croscarmellose sodium.

30 19. Use as claimed in any of the preceding claims wherein the rheology modifying agent is Ac-Di-Sol™.

20. Use as claimed in any of the preceding claims wherein the rheology modifying agent is present in an amount of at  
35 least 5 wt % of the component composition.

21. Use as claimed in any of the preceding claims wherein

the rheology modifying agent is present in an amount of at least 10 wt % of the component composition.

22. Use as claimed in any of the preceding claims wherein  
5 the rheology modifying agent is present in an amount of between from about 10 to about 40 wt % of the component composition.

23. Use as claimed in any of the preceding claims wherein  
10 the rheology modifying agent is present in an amount of about 20 wt % of the component composition.

24. Use as claimed in any of the preceding claims wherein  
the component composition further comprises sugar.  
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25. Use as claimed in Claim 24 wherein the sugar is lactose monohydrate.

26. Use as claimed in Claim 24 or Claim 25 wherein the  
20 sugar is present in an amount of between from about 30 to about 50 wt % of the component composition.

27. Use as claimed in any of Claims 24 to 26 wherein the  
sugar is present in an amount of about 35 wt % of the  
25 component composition.

28. Use as claimed in any of the preceding claims wherein  
the component composition further comprises cellulose.

30 29. Use as claimed in Claim 28 wherein the cellulose is microcrystalline cellulose.

30. Use as claimed in Claim 28 or Claim 29 wherein the  
cellulose is present in an amount of between from about 35  
35 to about 45 wt % of the component composition.

31. Use as claimed in any of Claims 28 to 30 wherein the

cellulose is present in an amount of about 30 wt % of the component composition.

32. Use as claimed in any of the preceding claims wherein  
5 the composition consists essentially of prednisolone or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

33. Use as claimed in any of Claims 1 to 31 wherein the  
10 composition consists essentially of metronidazole or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

34. Use as claimed in any of Claims 1 to 31 wherein the  
15 composition consists essentially of erythropoetin or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

35. Use substantially as hereinbefore described with  
20 reference to the accompanying examples.

36. A process for the production of particles for use in a pharmaceutical composition, said process comprising the steps of:  
25 mixing water with a component composition comprising at least a rheology modifying agent to produce a paste;  
extruding at least a portion of the paste to form extrudate;  
spheronising at least a portion of the extrudate to  
30 form spheronised particles; and  
drying at least a portion of the spheronised particles.

37. A process as claimed in Claim 36 wherein the amount of  
water used is between from about 180 to about 190 wt % of  
35 the weight of the component composition and, where the spheronising step uses a rotation 70 cm plate, the plate does not rotate at about 33 rpm.

38. A process as claimed in Claim 36 or Claim 37 wherein the process comprises any of the features defined in Claims 2 to 35.

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39. A process substantially as hereinbefore described with reference to the accompanying examples.

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